LeMaitre® VASCULAR

TRIVEX® Illuminator Inflow Tube Set

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Instructions for Use - English

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(Model Number 7209513)
Instructions for Use - English

STERILE EO Rx only

Please see the TRIVEX System Illuminator instructions for use (R2596).

Indications for Use
See the TRIVEX System Illuminator instructions for use (R2596).

Contraindications
See the TRIVEX System Illuminator instructions for use (R2596).

Warnings
- Do not resterilize. This product is provided sterile, for single use only. Do not reuse. Do not use after the expiration date. Prior to use, inspect the product package for structural integrity. Discard any opened and unused product. By purchasing any product designated for "single use," "multiple use in a single procedure," "do not resterilize," or the like, the customer agrees to limit that product's use in accordance with those express designations.
- As in conventional ambulatory phlebectomy procedures, bruising, hematoma, and hemosiderin deposits have been observed in clinical studies utilizing the TRIVEX system.

Precautions
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Prior to use, surgeons should become familiar with this surgical technique and the TRIVEX system.

Instructions for Use

Attaching disposable inflow tube set (ref 7209513) to irrigated illuminator (ref 7210351)
Follow operating room protocol for handling the tube set. Instructions are provided as reference only.
1. Circulator nurse
   - Offer packaged contents to scrub nurse.
2. Scrub nurse
   - Remove tube set from package.
   - Attach tube set to illuminator inflow port by inserting female luer fitting into male luer fitting and turning clockwise.
3. Circulator nurse
   - Close pinch clamps on tube set.
   - Spike fluid bag.
4. Scrub nurse
   - Open tube set clamp to establish flow.
   - To regulate fluid flow please see the TRIVEX system operations/service manual (R2601) for detailed instructions for use.

Limited Product Warranty; Limitation of Remedies
LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE)

AND HEREBY DISCLAIMS THE SAME. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

For Further Information

For further information if further information on this product is needed, please contact LeMaitre Vascular customer service at 1-800-628-9470 in the U.S., or your authorized representative.

Symbol Legend

		Distributed By:	**Rx only**
English	Symbol Legend	Distributed By	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.

LeMaitre®
VASCULAR

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